

ARC 2247R1

IN THE CLAIMS:

Please cancel claims 1, 2, 5 through 15, and 18 without prejudice or disclaimer. Please amend claims 19 and 20 as set forth below, and please add claims 21 through 36 as set forth below. Applicants note that all claims currently pending in the application are shown below for clarity, except claims 1, 2, 5 through 15, and 18, which are canceled herein.

Please cancel claims 1, 2, 5 through 15, and 18 without prejudice or disclaimer.

19. (Amended) A dosage form comprising:

a core comprising a drug formulation;

B1. an interior membrane formed around the core, the interior membrane comprising 35 wt% to 70 wt% of a polymer possessing a lipophilic-attracting property, 25 wt% to 65 wt% of a flux enhancer, and 0 wt% to 10 wt% of a surfactant; and

an exterior membrane formed around the interior membrane, the exterior membrane comprising 35 wt% to 70 wt% of a polymer permeable to the passage of an aqueous fluid, 10 wt% to 40 wt% of a plasticizer, 20 wt% to 35 wt% of a peptide, and 0 wt% to 10 wt% of a surfactant.

20. (Amended) The dosage form of claim 19, wherein the interior membrane contacts the exterior membrane, and an exit is present in the interior and exterior membranes for delivering the drug from the dosage form.

B2. 21. A sustained release dosage form comprising:

a core formulation; and

a bilayer membrane formed around the core formulation, the bilayer membrane comprising:

an interior lipophilic membrane; and

an exterior hydrophilic membrane comprising a compound possessing at least one peptide moiety, the exterior membrane being formulated to delay the disintegration of the

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interior membrane.

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22. The sustained release dosage form of claim 21, wherein the exterior hydrophilic membrane comprises:

20 wt % to 35 wt% of the compound possessing at least one peptide moiety;

35 wt% to 70 wt% of a semipermeable polymer;

10 wt% to 40 wt% of a plasticizer; and

0 wt% to 10 wt% of a surfactant.

23. The sustained release dosage form of claim 21, wherein the hydrophilic exterior membrane comprises:

20 wt% to 35 wt% of the compound possessing at least one peptide moiety;

35 wt% to 70 wt% of a member selected from the group consisting of a cellulose acylate, cellulose diacylate, and a cellulose triacylate polymer;

10 wt% to 40 wt% of a plasticizer that increases the aqueous diffusion coefficient of the exterior hydrophilic membrane and is selected from the group consisting of glycerin, triacetin, adipic acid, azelaic acid, citric acid, triethyl citrate, acetyl triethyl citrate, tributyl citrate, acetyl tributyl citrate, butyryl trihexyl citrate, polyethylene glycol, diethylene glycol dipelargonate and triethylene glycol di(2-ethylbutrate); and

0 wt% to 10 wt% of a surfactant.

24. The sustained release dosage form of claim 21, wherein the compound possessing at least one peptide moiety comprises 20 wt% to 35 wt% of the exterior membrane and comprises a protein possessing a molecular weight of 1500 to 350,000.

25. The sustained release dosage form of claim 22, wherein the surfactant is selected from the group consisting of an anionic, amphoteric, cationic and nonionic surfactant.

26. The sustained release dosage form of claim 21, wherein the compound possessing

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at least one peptide moiety comprises a member selected from the group consisting of reticulin, silk, keratin, casein, lactoglobulin, prolamine, gluten, albumin, elastin, soy protein, globulin, gelatin, collagen, and zein.

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27. The sustained release dosage form of claim 24, wherein the protein is sized between about 0.1 microns to 50 microns in one dimension.

28. The sustained release dosage form of claim 21, wherein the interior lipophilic membrane comprises:

35 wt% to 70 wt% of a lipophilic polymer;

25 wt% to 65 wt% of a flux enhancer; and

0 wt% to 10 wt% of a surfactant.

29. The sustained release dosage form of claim 28, wherein the lipophilic polymer comprises poly(ethyl cellulose).

30. The sustained release dosage form of claim 28, wherein the flux enhancer comprises hydroxyalkylcellulose, wherein the alkyl group comprises 1 to 6 carbon atoms.

31. The sustained release dosage form of claim 28, wherein the lipophilic polymer comprises poly(ethyl cellulose) exhibiting a viscosity of 3 to 350 centipoise.

32. The sustained release dosage form of claim 28, wherein the flux enhancer comprises a hydroxyalkylcellulose selected from the group consisting of hydroxyethylcellulose and hydroxypropylcellulose.

33. The sustained release dosage form of claim 28, wherein the surfactant comprises a member selected from the group consisting of polyoxyl 4 stearate, polyoxyl 8 stearate, polyoxyl 20 stearate, polyoxyl 30 stearate, polyoxyl 40 stearate, polyoxyl 50 stearate, polyoxyl 100

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stearate, polyoxyl 4 distearate and polyoxyl 150 distearate, and wherein the number refers to the surfactant polymer length in oxyethylene units.

34. The sustained release dosage form of claim 21, further comprising an exit through the bilayer membrane for delivering the drug from the dosage form.

35. The sustained release dosage form of claim 21, wherein the core formulation comprises a drug.

36. The sustained release dosage form of claim 21, wherein the core formulation comprises a drug and an expandable composition.

REMARKS

The Office Action mailed April 17, 2001 (hereinafter "the Office Action"), has been received and reviewed. Claims 1, 2, 5 through 15, and 18 through 20 are currently pending in the application, and each of claims 1, 2, 5 through 15, and 18 through 20 stand rejected. Applicants, however, have canceled claims 1, 2, 5 through 15, and 18 without prejudice or disclaimer. Further, Applicants have amended claims 19 and 20 and have added new claims 21 through 36. Thus, Applicants respectfully request reconsideration of the application in light of the amendments and remarks set forth herein.

35 U.S.C. § 112 Rejections

Each of claims 1, 2, 5 through 15, and 18 through 20 stand rejected under 35 U.S.C. § 112, first paragraph. However, because claims 1, 2, 5 through 15, and 18 are cancelled herein without prejudice of disclaimer, such rejection is discussed only as it relates to claims 19 and 20.

Applicants respectfully submit that the rejection of claims 19 and 20 under 35 U.S.C. § 112, first paragraph, should be withdrawn. The first paragraph of 35 U.S.C. § 112 states that